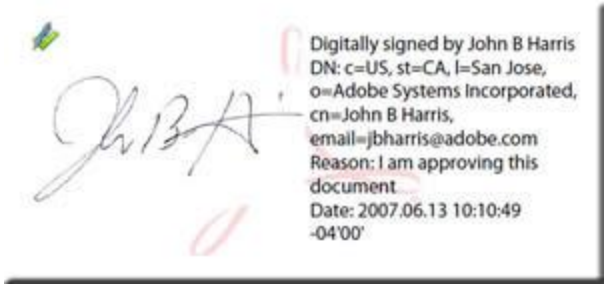
Electronic Signatures

Electronic signatures

Electronic signatures encompass a broad range of technologies and methodologies, ranging from an “I agree” button in a click-thru agreement…

to an electronic tablet which accepts a handwritten signature (oftentimes referred to as an *eSignature*)…

to a *digital signature* cryptographically tied to a digital ID or certificate

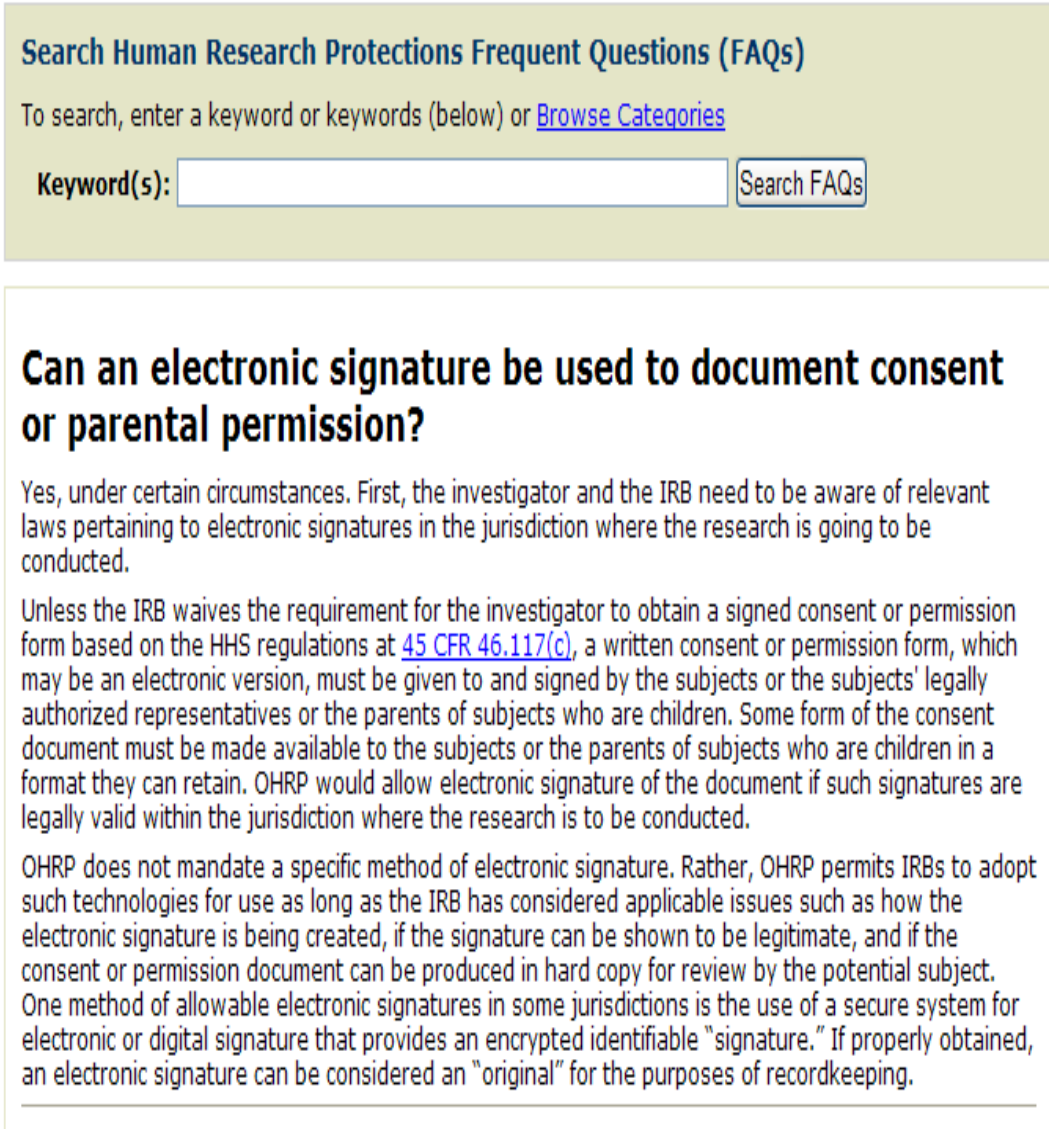


John B. Harris, Adobe Security blog entry "So what is an electronic signature anyway?", http://blogs.adobe.com/security/2008/02/so_what_is_an_electronis_signa.html

Will OHRP allow an electronic signature to be used to document informed consent?

YES

OHRP guidance on e-signatures



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Can an electronic signature be used to document consent or parental permission?

Yes, under certain circumstances. First, the investigator and the IRB need to be aware of relevant laws pertaining to electronic signatures in the jurisdiction where the research is going to be conducted.

Unless the IRB waives the requirement for the investigator to obtain a signed consent or permission form based on the HHS regulations at 45 CFR 46.117(c), a written consent or permission form, which may be an electronic version, must be given to and signed by the subjects or the subjects' legally authorized representatives or the parents of subjects who are children. Some form of the consent document must be made available to the subjects or the parents of subjects who are children in a format they can retain. OHRP would allow electronic signature of the document if such signatures are legally valid within the jurisdiction where the research is to be conducted.

OHRP does not mandate a specific method of electronic signature. Rather, OHRP permits IRBs to adopt such technologies for use as long as the IRB has considered applicable issues such as how the electronic signature is being created, if the signature can be shown to be legitimate, and if the consent or permission document can be produced in hard copy for review by the potential subject. One method of allowable electronic signatures in some jurisdictions is the use of a secure system for electronic or digital signature that provides an encrypted identifiable "signature." If properly obtained, an electronic signature can be considered an "original" for the purposes of recordkeeping.

OHRP FAQ:

- Does not require specific method of electronic signature
- Provides points to consider for the IRB to evaluate method of obtaining electronic signature
- "OHRP would allow electronic signature…if such signatures are legally valid within the jurisdiction where the research is to be conducted."
- Q: In what jurisdiction is the research being conducted?

Why is this a question?

- Multisite studies where investigator and subjects are not co-located
- Internet research where investigator may not know where subjects are physically located

Possibilities for jurisdiction

- Jurisdiction of researcher
- Jurisdiction of researcher and subject(s)
- Jurisdiction of subjects

Analogy to telemedicine?

- Where is practice of medicine?
- Where can a tort claim be brought?

- Is this a relevant analogy?

Some of the possibilities for guidance from OHRP

- Allow IRBs and regulated entities to make these determinations on their own without more specific OHRP guidance – status quo
- Provide a more specific statement in the FAQ:
  - E-signature that met requirements of jurisdiction of the researcher would satisfy the 46.117 documentation requirement; or
  - E-signature that met requirements of jurisdiction of the researcher and the subjects would satisfy the 46.117 documentation requirement

Investigator's knowledge of subjects locale relevant?

- If investigator knows where subjects are located, should this be a consideration?
- If investigator does not know – and perhaps cannot be sure of knowing -- where subjects are located (e.g. Internet research), should this be a consideration?

Keep in mind…

- OHRP guidance on point, if any, would only serve to explain what type of e-signature OHRP would consider to satisfy the requirements of the HHS protection of human subject regulations
- Other state/local laws, if any, still apply

- Value added by additional OHRP guidance?
- FDA's perspective?